REMARKS

This amendment is intended as a full and complete response to the final Office Action dated November 19, 2007. In the Office Action, claims 8-28 are pending, of which claims 8-10, 12-15, 20 and 22 are rejected, claims 23-28 are allowed, and claims 11, 16-19 and 21 are objected to. By this amendment, claim 11 is amended.

A teleconference between Examiner Cary O'Connor and the Applicant's representative, Steven M. Hertzberg, on February 7, 2008 is duly noted and appreciated. During the teleconference, the relevancy of the two cited prior art patents to Greenberg were discussed. The Examiner indicated that upon receiving this response a further search would be conducted, since the Examiner had just recently been assigned this application. In view of the aforementioned, if the new search conducted by the Examiner produces additional information requiring consideration, it is respectfully requested that a new Office Action be issued.

In view of the following discussion, it is submitted that none of the claims now pending in the application are anticipated or obvious under the respective provisions of 35 U.S.C. §102 and §103. Thus, it is believed that all of these claims are now in allowable form.

OBJECTIONS

A. Allowable Subject Matter:

Claims 11, 16-19 and 21 are objected to as being dependent upon a rejected base claim. The Office Action states that these claims would be allowable subject matter if rewritten in independent form including all the limitations of the base claim and any intervening claims.

The indication of the allowability of claims 11, 16-19 and 21 is duly noted and appreciated. However, in view of the arguments set forth herein, it is believed that base claims 8 and 20 (and all intervening claims) are in allowable form and, as such, all the dependent claims 9-19, 21 and 22, as they stand, are therefore in allowable condition. Therefore, it is respectfully requested that the foregoing objections to claims 11, 16-19 and 21 be withdrawn.

B. In the Specification:

The specification has been amended to provide minor typographical corrections. Such typographical corrections do not add any new subject matter to the application.

C. In the Claims:

Claim 11 has been amended to correct minor typographical errors. The correction of the typographical errors does not add any new subject matter to the application.

REJECTIONS

A. 35 U.S.C. §102

In the Office Action, it is stated that claims 20 and 22 are rejected under 35 U.S.C. §102 as being anticipated by US Patent No. 5,746,743 to Greenberg (hereinafter "the `743 patent"). The rejection is respectfully traversed.

As a preliminary matter, we believe that it would be helpful to review the appropriate standard under 35 U.S.C. § 102 for analyzing the features of a claim with respect to the prior art. It is well settled that "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim" (Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984)(citing Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added). The cited reference fails to disclose each and every element of the claimed invention, as arranged in the claim.

Independent claim 20 recites:

> A bur for performing a Caldwell-Luc osteotomy to penetrate a lateral wall of a maxillary sinus of a patient comprising:
>
> an elongated shaft having opposing first and second ends, said first end configured for insertion into a rotary device;
>
> a cutting blade coupled to the second end of said shaft; and
>
> a depth guide extending transversely from said shaft and spaced a predetermined distance from the distal end of said cutting blade. (Emphasis added).

Referring to FIG. 4 of the present application, the depth guide 402 extends transversely from the shaft 404 of the bur 400. In particular, referring now to FIG. 4, in another aspect of the present invention, a bur 400 with a depth guide 402 is then utilized to prepare the osteotomy within the outline of the window 808 inside the surgical guide 800. As shown in the drawing, the bur 400 includes an elongated shaft 404 having a cutting blade 406 affixed to an end of the shaft 404, as is well known in the art. The depth guide 402 is affixed transversely across the shaft at a distance of 10 mm from the endpoint (E) of the cutting blade 406, although such distance is not considered limiting. (See substitute specification, page 18, paragraph 0046, Emphasis added).

By contrast, the `743 patent discloses a sleeve 32 positioned coaxially over the cutting blade (i.e., drill bit) 36. In particular, the `743 patent discloses:

> The prior art drill guides and retractors and related surgical methods, while useful, are not entirely satisfactory for the procedure described above. A prior art drill guide for controlling the angle and the depth of a hole drilled into anatomical bone is disclosed in a catalog published in 1992 by Synthes Maxillofacial, a surgical supply company located in Paoli, Pa. This drill guide 30 is depicted in FIG. 4. The drill guide 30 has a threaded inner sleeve 32 which is screwed into a first opening 34a of an outer sleeve 34. By rotating the inner sleeve 32 with respect to the outer sleeve 34, the inner sleeve 32 may be extended from, or retracted into, the outer sleeve 34. A knurled nut 33 is provided which may be loosened to permit the rotation of the inner sleeve 32. After the inner sleeve 32 is adjusted to a desired length from the outer sleeve 34, the knurled nut 33 may be tightened to prevent rotation of the inner sleeve 32. The length is adjusted so that only a desired portion of a drill bit 36 extends beyond a proximal end of inner sleeve 32 when a quick coupling (or "chuck") 37 of a drill 38 is contacting a distal end of the outer sleeve 34. The outer sleeve 34 is attached to, and integral with, a handle 35. The outer sleeve 34 and handle 35 are connected so as to form an obtuse angle.

Accordingly, the `743 patent at best discloses a sleeve 32 coaxially positioned over the shaft of the drill bit 36 and the sleeve 32 can be adjusted so that only a desired portion of a drill bit 36 extends beyond a proximal end of inner sleeve 32. Nowhere in the `743 patent is there any disclosure of "a depth guide extending transversely from said shaft and spaced a predetermined distance from the distal end of said cutting blade." The inner sleeve 32 of the `743 patent fails to disclose, or even suggest, a depth guide extending transversely from said shaft. Therefore, the `743 patent fails to disclose each and every element of the claimed invention, as arranged in the claim.

As such, it is submitted that claim 20 is not anticipated and fully satisfies the requirements under 35 U.S.C. § 102 and is patentable thereunder. Furthermore, claim 22 depends from independent claim 20 and recites additional inventive features. As such, and for at least the same reasons discussed above, it is submitted that these dependent claims also fully satisfy the requirements under 35 U.S.C. § 102 and are patentable thereunder. Therefore, withdrawal of the rejection is respectfully requested.

B. 35 U.S.C. §103

In the Office Action, it is stated that claims 8-15 are rejected under 35 U.S.C. §103 as being obvious over US Patent No. 5,746,743 to Greenberg (hereinafter "the `743 patent") in view of US Patent No. 5,558,622 to Greenberg (hereinafter "the `622 patent"). The rejection is respectfully traversed.

As a preliminary matter, we believe that it would be helpful to review the appropriate standard under 35 U.S.C. § 103 for analyzing the features of a claim with respect to the prior art. It is well settled that [t]he test under 35 U.S.C. § 103 is not whether an improvement or a use set forth in a patent would have been obvious or non-obvious; rather the test is whether the claimed invention, considered as a whole, would have been obvious. Jones v. Hardy, 110 USPQ 1021, 1024 (Fed. Cir. 1984) (emphasis added). Thus, it is impermissible to focus either on the "gist" or "core" of the invention, Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 230 USPQ 416, 420 (Fed. Cir. 1986) (emphasis added). Moreover, the invention as a whole is not restricted to the specific subject matter claimed, but also embraces its properties and the problem it solves. In re Wright, 6 USPQ 2d 1959, 1961 (Fed. Cir. 1988) (emphasis added).

Independent claim 20 recites:

> Surgical guide for performing a Caldwell-Luc osteotomy to penetrate a lateral wall of a maxillary sinus of a patient comprising:
>
> a curvilinear-shaped structure for placement adjacent said lateral wall of the maxillary sinus, said curvilinear-shaped structure having a window for exposing a corresponding portion of said lateral wall of the maxillary sinus to perform said osteotomy, said curvilinear structure and window being dimensioned and shaped based on a treatment plan for said patient that includes a CT scan and three-dimensional imaging which characterizes a plurality of walls defining the maxillary sinus and maxillary bone of the patient in three dimensions. (Emphasis added).

Referring to page 17, paragraph 0044 to page 18, paragraph 0045 of the present application discloses that:

> Referring now to FIG. 8, the surgical guide 800 is curvi-linear in shape and is sized and shaped to correspond to the upper jaw (maxilla) and sinus shape of a particular patient, as determined by the CT scan and 3-D imaging software previously administered to the patient. As illustratively shown in the drawing, the surgical guide 800 includes a curved lower portion 802 having an upper surface 804 adapted for positioning along the lower edge of the maxilla (alveolar ridge) or the upper teeth (e.g., molars). The curved lower portion extends in an upward direction to form a second portion 806 having an overall height "H" an, overall width "W", and an overall thickness or depth "D".
>
> The upward extending second portion 806 includes at least one orifice or window 808 illustratively having a somewhat rectangular shape. The peripheral edges of the window 808 form a ledge 810 that is used in conjunction with a bur (FIG. 4) for performing the osteotomy, as discussed below in further detail. The size and shape of the window 808, as well as the depth or thickness of the ledge 810 are formed to correspond with the results of the CT scan and 3-D imaging software used for planning the osteotomy for a particular patient, such that the lower portion of the ledge 810 is aligned with and conforms to the shape of the bony floor of the sinus cavity and coronal portion of the maxilla. (Emphasis added).

By contrast, the `622 patent discloses:

> [A] mandibular retractor which is inserted into the patient's mouth and has a curvilinearly-shaped retractor blade to retract the cutaneous region away from the mandible laterally. The retracting blade has an aperture which allows surgical instruments

> to be inserted through an incision in the cutaneous region, through the aperture, and to the mandible. The retractor also has an arcuate distal portion which may be located under and behind the mandible. The retractor allows a surgeon to retract with one hand and view the surgical site by looking down in to the mouth. The surgeon's other hand is free to operate surgical instruments such as a drill or screwdriver. (See `622 patent, col. 3, lines 25-37, emphasis added).

The mandibular retractor of the `622 patent is not capable of being used to perform a Caldwell-Luc osteotomy, since the shape of the retractor is designed to retract the cutaneous region away from the mandible (lower jaw bone) laterally. By contrast, the present invention is a surgical guide having a dimension and shape for performing a Caldwell-Luc osteotomy to enter the maxillary sinus as part of the procedure of sinus elevation and grafting. The maxillary sinus is located above the maxillary bone, i.e., the upper jaw bone, as opposed to the mandible (lower jaw bone). Accordingly, the shape and dimensions of the mandibular retractor of the `622 patent does not coincide with the different shape of the surgical guide of the present invention.

Even if the mandibular retractor of the `622 patent could somehow be used to perform a Caldwell-Luc osteotomy, and it is submitted that it can not be used for such surgical operation for the reasons described below, the mandibular retractor is not shaped and dimensioned (i.e., uniquely customized) based on the CT scan and 3-D imaging software results of the sinus area for each patient to allow the surgeon to accurately prepare a Caldwell-Luc osteotomy in all three planes (i.e., three-dimensions). Rather, the use of the mandibular retractor of the `622 would increase the risk of damaging the sinus membrane (Schneiderian membrane) positioned over the maxillary bone of a patient. (See Applicant's substitute specification, page 2, paragraph 0004 to page 4, paragraph 0006).

In particular, the mandibular retractor of the `622 patent is symmetrical in shape and includes a symmetrically shaped aperture 60 that is oval and is sized to receive a drill guide. The length, width and thickness (depth) along the periphery of the aperture 60 is constant in all three dimensions without any regard to the shape of the maxillary bone an sinus. Nowhere in the mandibular retractor of the `622 patent is there any disclosure or suggestion of a "curvilinear structure and window being dimensioned and shaped based on a treatment plan for said patient that

includes a CT scan and three-dimensional imaging which characterizes a plurality of walls defining the maxillary sinus and maxillary bone of the patient in three dimensions."

As described in the specification of the present application:

> [p]reviously, this procedure was performed merely with an approximation as to where the floor of the sinus was, where the superior portion was, as well as where the anterior wall and the posterior wall are located. In addition, the variable depth of the lateral wall of the sinus was accessed only with the experience and visual sense of the clinician without exact measurements as to the varying thickness of the osteotomy as it moved along the x-y axis. The proposed surgical guide eliminates all approximations of the osteotomy in the x-y axis as to the outline of the osteotomy, as well as along the Z axis as to the depth of the osteotomy so as to prevent any damage of overcutting into the Schneiderian Membrane, and thus enabling easy access into the sinus cavity as outlined by the treatment plan set forth utilizing 3-D imaging software from a CT scan of the patient's maxillary sinus. (See substitute specification, page 8, paragraph 0015).

Accordingly, the applicant's surgical guide differs from the mandibular retractor of the `622 patent because the shape and dimensions of the surgical guide of the present invention are customized and unique to each patient. The shape and dimensions are determined based on utilizing 3-D imaging software from a CT scan of the patient's maxillary sinus. Thus, the length, width and depth of the present invention (i.e., dimensions and shape) of the surgical guide and the aperture vary along each dimension to coincide with the unique shape of the maxillary bone of a patient. By contrast, the mandibular retractor of the `622 patent is not customized with a unique shape and dimensions based on a particular patient's maxillary bone structure. A surgeon that would attempt to use the mandibular retractor of the `622 patent for a Caldwell-Luc procedure would clearly have to approximate where the floor, superior portion, anterior portion, as well as the posterior portion of the maxillary bone and sinus are located.

Moreover, since no two patients have exactly identical bone structures, the mandibular retractor of the `622 patent does not address and solve the problems of the prior art surgical guides in a manner as set forth by the present invention. Specifically, the prior art surgical guides, including the mandibular retractor of the `622 patent even if it could somehow be used for such Caldwell-Luc procedure, involves reflecting a full thickness mucosal flap to expose the lateral wall of the sinus and maxilla. A lateral osteotomy is then prepared in the lateral wall of the maxillary sinus.

For example, as described in the Background of the Invention beginning on page 2, paragraph 0004 to page 7, paragraph 0012:

> "One of the technical difficulties encountered during this procedure is the inability of the operator to precisely locate the floor of the sinus as he prepares the osteotomy from an antero-posterior direction (along the X-Y axis). Since the floor of the sinus can elevate and descend variably as the osteotomy moves antero-posteriorly, it is impossible to visualize this course. Therefore, the osteotomy is generally prepared in a straight line higher than the highest point of the sinus floor. This guarantees penetration into the sinus floor since an osteotomy that is lower than the sinus floor at any point will simply penetrate into the maxillary bone and not into the sinus cavity. This would require adjustment by expanding the osteotomy superiorly (apically) in order to penetrate the sinus cavity. Obviously, the additional trimming of bone is traumatic and removes bone unnecessarily.
>
> Another error occurs if the osteotomy is placed too superior to the floor of the sinus. Very careful manipulation must then be effected in order to negotiate the remaining lateral wall of the sinus inferior to the osteotomy and to descend below the Schneiderian membrane in order to elevate it from the sinus floor. This technically difficult maneuvering of the instruments along two planes increases the risk of tearing the membrane and thus compromising the outcome of the graft. Otherwise, the osteotomy must be adjusted by expanding in an inferior direction. This would lead to additional trimming of bone and increase the risk of tearing the membrane during the expansion of the osteotomy. It is nearly impossible to visualize the variable course of the sinus floor as the osteotomy progresses antero-posteriorly. This inability to visualize the course of the sinus floor is the first difficulty encountered in the procedure.
>
> Another difficulty encountered is the varying thickness of the lateral wall of the sinus as the osteotomy penetrates it to expose the underlying Schneiderian membrane. The operator must penetrate fully through the lateral wall (X-Z axis) in order to raise the window and elevate the membrane. However, if the osteotomy is prepared too deep, it can tear through the fragile membrane. Therefore, great operator skill is required to visualize the membrane as the osteotomy is prepared through a varying depth of the lateral wall and the membrane is approached.
>
> A further difficulty encountered is the anterior wall of the sinus. Besides the varying depth of the lateral wall, the anterior wall can also vary in course in the Y-X axis (FIG. 2) just as the floor can vary in course in the X-Y axis (FIG. 2) and the lateral wall can vary in thickness in the Y-Z axis (FIG. 3). Since the osteotomy usually is placed in a straight line apico-coronally (vertically), whereas the anterior wall is usually not a straight line, portions of the osteotomy would be too far posterior to the anterior wall. This would require manipulation anteriorly and then laterally to dissect the membrane from the lateral and anterior walls thus increasing the risk of tearing the membrane from the difficult manipulation in two planes. Again, any additional adjustments to the osteotomy would cause unnecessary bone removal and trauma as well as increase the risk of tearing the membrane.

> Most of this technique relies on the careful approximation of the outline of the area of the sinus to be grafted. The osteotomy planned should be inside the sinus borders for reasons explained above. Since it is nearly impossible to accurately follow the varying course of the sinus during the osteotomy, inevitably there would be areas that are not exposed by the osteotomy. This would require the careful manipulation of the sinus membrane which risks damage to the membrane. Furthermore, as the lateral wall of the sinus is being cut, the varying thickness of the lateral wall requires that the surgeon proceed very carefully and rely on visual as well as tactile senses to establish that the wall has been pierced without entering the sinus so as to not damage the immediately underlying membrane. ... .
>
> Even with the information provided by the CT scan utilizing the 3-D imaging software as to the outline of the sinus in the X, Y and Z planes and all other parameters, there has been no mechanism to accurately transfer this highly precise information to the surgical field. Meticulous planning of the parameters of the sinus to be elevated and augmented has been thwarted by the inaccurate approximation in the transfer of this information during the surgical procedure.
>
> There has thus been a gap between the extremely precise diagnostic information and treatment planning obtained by the CT scan and 3-D imaging software, and the accurate transfer of that information into the surgical field to aid the surgeon in executing such a treatment plan."

Accordingly, the surgical guide of the present invention overcomes the limitations and drawbacks of the mandibular retractor of the `622 patent, and solves the problems associated with the previously used surgical guides. Specifically, the surgical guide of the present invention provides a significant contribution to the state of the art of reconstructive surgery of the maxillary sinus by providing a surgical guide that advantageously transfers precise data obtained from a CT scan utilizing 3-D imaging software (i.e., dimension and shape) into the surgical field and aids the surgeon in such surgery.

Therefore, since the `622 patent fails to disclose or suggest "curvilinear structure and window being dimensioned and shaped based on a treatment plan for said patient that includes a CT scan and three-dimensional imaging which characterizes a plurality of walls defining the maxillary sinus and maxillary bone of the patient in three dimensions, the `622 patent fails to disclose or suggest the present invention as a whole.

As such, it is submitted that claim 8 is not obvious and fully satisfies the requirements under 35 U.S.C. § 103 and is patentable thereunder. Furthermore, claims 9-15 depend, either directly or indirectly, from independent claim 8 and recite additional features thereof. As such,

and for at least the same reasons discussed above, it is submitted that these dependent claims also fully satisfy the requirements under 35 U.S.C. § 103 and are patentable thereunder. Therefore, withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the amendment and discussion presented herein, it is respectfully submitted that the present Amendment responds to all of the issues raised in the Office Action. Thus, it is submitted that all of the claims are in condition for allowance. Accordingly, reconsideration of this application and its prompt passage to issue are earnestly solicited.

If, however, the Examiner believes that there are any unresolved issues in any of the claims now pending in the application, we respectfully request that the Examiner telephone Steven M. Hertzberg at (212) 885-9223 so that appropriate arrangements can be made for resolving such issues as expeditiously as possible.

The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, due by reason of this Amendment to Deposit Account No. 01-0035.

All correspondence should continue to be directed to the address below.

Respectfully submitted,

ABELMAN, FRAYNE & SCHWAB
Attorneys for Applicant

Steven M. Hertzberg
Reg. No. 41,834

ABELMAN, FRAYNE & SCHWAB
666 Third Avenue
New York, New York 10017-5621
Tel: (212) 949-9022
Fax: (212) 949-9190